July 8, 2005

BY FAX AND EMAIL

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, California 95812-4010

Re: Comments on Three Different Regulatory Proposals Concerning Acrylamide

Dear Ms. Oshita:

The Environmental Law Foundation submits these comments on behalf of the California League of Environmental Enforcement Now (CLEEN) and its members on the three proposed regulations dealing with acrylamide in food. We provide these combined comments because some comments apply to all three proposals, while others are related but regulation-specific. They should be entered into the regulatory file for each proposed regulation.

The California League of Environmental Enforcement Now is a statewide coalition of environmental and public health organizations, advocates and law firms committed to protecting and strengthening laws regulating toxic pollution and keeping drinking water safe. The members of CLEEN include the Environmental Law Foundation, Citizens for a Better Environment, Center for Environmental Health and others. The complete list is included in the final page.

Sincerely,

Alise Cappel

Table of Contents

I. General Comments Concerning Regulatory Actions for Acrylamide in Food

A. The Acrylamide Problem in Perspective

Before any regulatory action is undertaken, the true nature of the perceived problem must be accurately characterized. CLEEN submits that the acrylamide problem can be summarized in three simple statements:

- The cancer risk from acrylamide in food is real.
- The cancer risk from acrylamide in food is limited.
- The problem of high levels of acrylamide in food is solvable.

Industry's approach to the acrylamide problem mirrors its approach to Proposition 65 generally in the nearly twenty years it has been law. Claim the law wrong and misguided; claim that "everything will require warnings"; claim the warning requirement will mean ruin for industry and consumer alike; and therefore demand the law not be applied to the food industry, or that it be applied in such a way as to entirely undo the law's commands. A sober look at the acrylamide problem reveals that once again the industry is crying wolf.

1. The cancer risk is real

As the Office of Environmental Health Hazard Assessment's ("OEHHA") revised No Significant Risk Level ("NSRL") document makes clear, cancer risk from acrylamide exposure in the diet is regarded throughout the world as a "major concern".[1] And while there is ongoing debate about the extent of the problem, exposure scientists throughout the world agree that for acrylamide, cancer is the most sensitive endpoint. In the media, however, the food industry is telling a different story. They argue that acrylamide is really nothing to worry about, that only "trace" amounts of the chemical are found in foods, the implication being that trace amounts will not do us harm.

This characterization is not only false but entirely irresponsible. Research funded and recently released by The Environmental Law Foundation shows that the cancer risk from ingestion of acrylamide, at least for one class of foods, is very real. These data show that acrylamide levels in popular potato chip products are 1.5 to 2.5 times greater than the highest level found in any potato chip product by the United States Food and Drug Administration ("US FDA").[2] Assuming consumption to be 28 grams per day, cancer risk for the products with the highest acrylamide concentrations is estimated to be between 1 and 2 excess cases of cancer per 1,000 people. That's 1,000, not 100,000 and even the most conservative exposure scientists will agree that cancer risk

---

[1] FAO/WHO Consultation on the Health Implications of Acrylamide in Food (June, 2002). http://www.who.int/foodsafety/publications/chem/en/acrylamide_summary.pdf

[2] Environmental Law Foundation, *How Potato Chips Stack Up: Levels of Acrylamide in Popular Brands of Potato Chips* (June, 2005). http://www.envirolaw.org/report_how_potato_chips_stack_up.pdf

this high, especially from popular, widely consumed food products, is unacceptable.

2. The cancer risk is limited

Although the food industry would have us believe otherwise, acrylamide is not ubiquitous in the food supply. Rather, the risk of acquiring cancer from acrylamide in the diet is clearly limited to the consumption of specific foods.

First, it occurs in a limited percentage of the food supply. As one advocate representing a large coalition put it at a public workshop before this agency, the acrylamide issue affects "only a sliver of the food supply."

Second, even among the types of foods in which acrylamide appears, the concentrations of acrylamide vary widely among different food products, with variances exceeding orders of magnitude. Hence, cancer risk estimates can vary significantly from product to product across each class of foods in which acrylamide appears. Attention should be directed to the specific foods with the highest concentrations that pose the highest cancer risk. Therefore the agency needs to be careful that it not be stampeded into action by the specter of "everything requires a warning" or industry's tactic of using some foods with de minimis acrylamide levels to act as cover for those foods with high acrylamide levels. In other words, the fact that acrylamide is present in low concentrations in a large number of foods should not be used as justification for any regulatory measure that will hide from the public the fact that a smaller number of foods have exceedingly high concentrations of acrylamide.

When acrylamide is present at levels high enough to deserve consumer warnings about cancer it is almost entirely limited to foods containing grains or starch, and then only to foods that are highly heat-processed convenience foods manufactured and packaged for sale. The US FDA survey of foods that contain acrylamide reveals that those foods with the highest levels in the average diet fit that description. The US FDA estimates that fully 40% of acrylamide intake results from just four food products: french fries, breakfast cereals, potato chips and "store bought" cookies.[3] These are foods that for the most part are prepared systematically by manufacturers using carefully controlled and consistent ingredients and processing techniques, and which require little or no further action by the consumer.

3. The problem of acrylamide in food is solvable

The food industry avers that acrylamide is not only a ubiquitous problem, but also that it can not be controlled, at least to levels in foods below the current NSRL (or any updated figure). This is simply untrue. Researchers throughout the world have already discovered several methods whereby the presence of acrylamide can be reduced in different food products.

---

[3] DiNovi, M., Howard, D. *The Updated Exposure Assessment for Acrylamide* (April, 2004). Presentation Prepared for the 2004 Acrylamide in Food Workshop Sponsored by the Joint Institute for Food Safety and Applied Nutrition. http://www.jifsan.umd.edu/acrylamide2004.htm.

Research has demonstrated that acrylamide levels in potato chips can be reduced by a number of processes including, but not limited to: (1) choosing different varieties of, for example, the potato used in potato chips; (2) avoiding sugar dips or coatings in partially cooked products; (3) increasing product moisture; (4) lowering the pH during processing; (5) storing ingredients or products at higher temperatures; (6) changing temperature and cooking regimes; (7) cooking products at lower temperatures; (8) adding asparaginase; (9) replacing ammonium; and, (10) changing cooking oils.[4]

The point is not that there is a single obvious solution for all products. The point is that without regulatory incentive food manufacturers in the United States will not voluntarily pursue further research into means to reduce the levels of acrylamide in products or actually implement the results of that research. The evidence for this is abundant. For the past three years, despite numerous reports in the scientific and industry literature about feasible methods for reducing acrylamide in foods, no U.S. food manufacturer has publicly committed to using any specific method to reduced acrylamide levels in any product.[5] Instead, the food industry has chosen to spend its considerable resources lobbying the US FDA, OEHHA and the Governor of California to instead exempt it from the Prop 65 warning requirement.

B. Any Regulatory Solution Must Adhere to Three Principles

Rather than unsupported speculation and bad science, as a matter of sound public health policy (and the law), any regulatory solution must adhere to three principles. Any policy must:

1. be scientifically justifiable and defensible;

2. provide incentives to industry to reduce acrylamide levels in food products, and not to hide the presence of the chemical;

3. provide "clear and reasonable warning" information to consumers.

Examples of how the three proposed regulatory actions violate one or more of these principles and how they might be amended to achieve them instead are provided below.

---

[4] European Commission, *Note of the Meeting of Experts on Industrial Contaminants in Food Acrylamide Worship, 20-21 October 2003 Information on Ways to Lower the Levels of Acrylamide Formed in Food* (October, 2003). http://www.europa.eu.int/comm/food/food/chemicalsafety/contaminants/acryl_guidance.pdf

[5] One glaring exception is the Procter and Gamble company, manufacturer of Pringles Potato Crisps. One variation of Pringles in the US FDA data had the second single highest concentration of acrylamide in any item that was edible. Furthermore, Pringles was among the products for which a Proposition 65 notice of violation was recently filed by the Environmental Law Foundation. In public comments, a Procter &Gamble spokesperson said that the company was exploring (unidentified) means to reduce acrylamide levels in Pringles. *See*, Groom, Nicola. "Consumer group wants warning label on potato chips," Reuters, 17 June 2005. www.reuters.com/newsArticle.jhtml?type=healthNews&storyID=8827095.

C. The Need for Immediate Regulatory Action is Doubtful

The public and nonpublic actions taken by the food industry strongly suggest that the industry itself does not believe any regulatory action is necessary. At minimum it suggests a rank level of hypocrisy that needs to be exposed and discarded before this agency takes any action.

1. Industry's Public Inaction Belies the Need for Any Action

It is notable that not a single foodstuff that these commenters could find contains any warning about acrylamide. Not one. That is, the industry is clamoring for regulatory action by the agency is asking to be relived of the obligation to give warnings that in fact they are not giving. Acrylamide in foods was first reported in 2002 and has been reconfirmed by national and international agencies and researchers in certain foods for three years. Yet not one product contains a warning about acrylamide.

But since the industry is not in fact providing any warnings, it is difficult if not impossible to determine what the true effect any of these regulatory actions would be. And the industry has resolutely refused to share any data with the agency about what levels of what chemicals occur in what foods, or what the consumption data of those foods are, making it impossible to evaluate when and where these regulatory proposals might have an effect, or what the collateral public health and consumer choice implications will be.

Where an industry by word and deed demands that an agency act, it is incumbent on that industry to provide as much data and information as possible to inform the agency. Put another way, regulating in the dark is folly.

2. Industry Representatives Don't Believe An Exemption Is Legally Necessary

In addition to public actions resulting in not a single warning on any food, industry representatives have simultaneously been clamoring for an exemption that they privately contend they do not need.

Major representatives for the food industry and trade associations that were present at the May 9 workshop on the industry's exemption proposal have privately opined, but apparently will not say publicly, that they believe the statute and existing regulations provide ample legal justification for not giving any warning about acrylamide. Given this dichotomy between their public and private postures, the agency can and must demand that the industry explain its full legal position on whether or not warnings are legally required for acrylamide in food. Publicly they claim they need an exemption; privately they say they already have it.

Again, the agency should not take any regulatory action whatsoever unless it is fully informed of the true legal and policy consequences of the action, by the very party calling for action.

II. Comments on Amendment to 12705. Establishment of 12705(b), A Specific Regulatory Level Posing No Significant Risk for Acrylamide

A. The Revised NSRL is Scientifically Defensible but Lacking An Essential Component

The updated NSRL is scientifically defensible but lacking an essential component: it does not address how children and other sensitive populations may differ in their susceptibility to acrylamide. This is particularly problematic since some of the foods at issue – sugary breakfast cereals, many snack foods – are targeted to and consumed largely if not exclusively by children. However, due to acknowledged data gaps in available animal toxicity data, OEHHA forthrightly acknowledges that "the cancer potency derived may not be adequately protective of children and other sensitive groups."[6] That document implies the NSRL will need to be revised once animal data is available to allow OEHHA to evaluate cancer risks from acrylamide for children and sensitive populations.

Given this fact, if OEHHA chooses to amend the NSRL, it may instead choose to adopt a differential NSRL – one for exposures (in food or elsewhere) to the adult population or the population at large, a second, more stringent level (perhaps the existing NSRL) where exposures occur in foods marketed for consumption by children.

III. Comments on Amendment of 12705. Addition of 12705(e), a New Subsection Providing an Alternative Risk Level for the Chemical Acrylamide in Breads and Cereals

A. The Alternative Risk Level is Not Based on Sound Science

The proposal for an alternative risk level for breads and cereals to an unprecedented 1/10,000 cancer risk is not based on sound science. Indeed, it is not based on any science at all.

Before deciding anything of this magnitude regarding the health of Californians, a regulatory proposal must have compelling scientific justification and be based on strong data. The rationale for an alternative risk level for breads and cereals is that consumers will react, en masse, to any warnings by avoiding all foods with warnings, and thereby deprive themselves of foods essential to good nutrition and a healthy diet. Let us examine that rationale in detail.

First, that rationale is not based on compelling or strong data. In fact, the rationale for raising the cancer risk level for breads and cereals is based on no science at all, but rather, on pure speculation. Not one shred of scientific or other evidence has been put forth to support the notion that cancer warnings on bread and cereal products will cause consumers to avoid foods that are necessary for a balanced diet. Oddly, this rationale, found in US FDA documents, is directly contradicted by the main argument put forward by food industry representatives. They argue that cancer warnings for acrylamide will be so widespread as to have the opposite effect, that consumers

---

6. Office of Environmental Health Hazard Assessment, *The No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Acrylamide* (March, 2005) pp. 1 and 23.

will fatigue of seeing cancer warnings on too many foods and will disregard the warnings altogether. Where an unprecedented policy is offered, one that has the potential to hide serious, demonstrated cancer risks from the public, there must be some data to show the policy is in fact justified.

Second, where the rationale is unsupported by data, and it is directly refuted by (some) of the affected industry's arguments (i.e., that many warnings will negate any consumer response), the agency should tread cautiously before acting.

Third, as discussed in detail below, it is not clear that OEHHA's mandate as a "lead agency" under Prop 65 includes a general mandate to manipulate consumer behavior. OEHHA has no expertise in consumer behavior regarding food, consumption patterns, the overall diet or general concerns about dietary choices and nutrition. OEHHA would need far more data and expertise to determine whether, in fact, allowing a cancer risk that is a full order of magnitude higher than any other Prop 65 cancer risk will prevent consumers from eating foods necessary for a balanced diet. This belief is based on pure supposition. How is OEHHA to know that a ten-fold increased cancer risk is the right level of risk to protect consumers from their own (apparently) bad choices. How can OEHHA justify a ten-fold increased cancer risk when they know that children's exposures to acrylamide are estimated to be greater than adult exposures and when they believe the cancer potency factor they derived is inadequate to protect children and other sensitive populations.[7]

Fourth, OEHHA should not act to carve out a class of consumer exposures for which an increased cancer risk will be hidden from consumers without identifying, with specificity and based on comprehensive data, what products will be affected. As the affected group, consumers of breads and cereals deserve to know that they are eating foods that will not trigger the 1/100,000 cancer risk warning threshold. Oddly enough, OEHHA must identify the products whose ten-fold increased cancer risk will be concealed in order to insure that consumers know which are the foods OEHHA believes should be consumed as part of a balanced diet. To do any of this, however, requires comprehensive data on acrylamide levels in specific food products across the entire spectrum of foods in which acrylamide appears. As OEHHA admits, there is no long-term data on the frequency of consumption for the foods we about now that contain acrylamide. Bearing this in mind, a scientifically defensible alternative NSRL for breads and cereals would then need to be based on truly reliable daily consumption data of all foods that contain acrylamide. Again, as OEHHA's Intake Characterization makes clear, for most foods, the data are rather weak. Therefore, without a comprehensive and reliable data set, OEHHA simply has no idea what effect the proposed regulation might or will have.

In sum, the rationale for the proposed regulation has no known basis other than speculation and introspection, and even if adopted OEHHA has no means to know whether the regulation will have the desired effect, or what foods and therefore what health effects it will have. In short, to be perfectly candid, OEHHA has no way to predict the outcome if it adopts this regulation. In the face of such a massive scientific data gaps, any action is a crapshoot.

B. The Alternative Risk Level Sets Bad Precedent and Subverts the Statute's Intent

---

[7] Office of Environmental Health Hazard Assessment, *The No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Acrylamide* (March, 2005) pp. 22 and 23.

The document entitled "Characterization of Acrylamide Intake from Certain Foods" authored by OEHHA "to guide efforts to interpret the applicability of Proposition 65 to acrylamide in foods" is entirely unnecessary and sets bad regulatory precedent. Put simply, it appears to introduce concepts of risk assessment into the warning calculation and subverts the intent of the statute.

Prop 65 operates so that the kinds of risk assessment found in other federal and state regulatory regimes for air and water and other media is entirely unnecessary in determining whether or not a warning is required. In fact, by design, the statute and the regulation 12721(c) were written to relieve California businesses from the burden of doing expensive and time consuming risk assessments to determine whether or not a warning is required in a given circumstance. Thus, for instance, by establishing "safe harbor" exposure numbers, a company need only determine (a) what concentration of the listed chemical is present in the given medium of exposure and (b) how much of the given medium is the individual exposed to in a given exposure. That's all. Nothing more is required. No long term epidemiological studies. No long term exposure analyses. Simply concentration and amount.

But this document introduces risk assessment into the warning calculation. In so doing, OEHHA's Acrylamide Intake Characterization document turns the intent of the statute on its head. The statute is clear: warn before exposure. That warning requirement obtains before the exposure and is not dependent on what exposures to that medium or chemical might occur later.

In the case of food, there is no possible way to measure the frequency of consumption of any given food over a lifetime, because there is no way to know, to predict or even to measure how often human beings will consume any specific food in the future. The same is true for many exposures. For instance, in an environmental exposure to a listed chemical in air, there is no way to know how long a person who lives or work nearby will continue to live or work, or even whether the business will continue in present form, output and processes in that location. But the obligation to warn on any given day is not dependent on any future events or exposures to determine what the risk level will in fact be over the exposed individual's lifetime.

Instead, the statute is explicitly structured to relieve the agency and business of even trying to make such calculations. The statute states, unequivocally, that the business (and agency) must simply "assum[e] lifetime exposure at the level in question." This does not permit the agency to calibrate the warning requirement for any given exposure by making assumptions about what the next or future exposure might be, or when. Put simply in the environmental air exposure example, the obligation to warn about exposure today is based on the level of the listed chemical in the air today. A business cannot expose the neighborhood one day to six times the level at which a warning is required on the rationale that it will be closed the rest of the week. To put it simply, the statute expressly requires the assumption that the "level in question" will continue, and the business does not get credit for all the days no exposure occurs.

This is sensible in light of Prop65's purposes, particularly when compared to the purposes underlying other regulatory regimes. Prop 65 does not attempt to regulate or calibrate the occurrence of cancer from given media or exposures or chemicals. It is first and last a warning statute. It is designed to give people clear and reasonable warnings about exposures to known

carcinogens above a certain threshold. That is all. Choices – and the actual levels of resulting cancer – are left to consumers. OEHHA does not have the authority to attempt to calibrate what levels of the listed chemicals should appear in any given medium, nor the frequency of the exposures, nor measures to control the exposures, nor even the resulting cancer risks or occurrences. All of that lies outside OEHHA's control and mandate. Hence trying to use tools of risk assessment to set warning levels makes no legal, regulatory or scientific sense.

In sharp contrast, other regulatory regimes that deal with toxins in air, water or consumer products seek to do precisely that: regulate the precise level of the toxin permitted in the air, water, product or workplace in order to achieve a precise level of cancer incidences. Those are health statutes, not warning statutes. Hence they need to use the tools of risk assessment because they are seeking to manipulate and control that risk to achieve a desired outcome. Prop 65 bears no such burden. The task is so much simpler – determine when to warn.

Thus, for food, the assumption *de jure* is that an average amount of the medium – a specific amount of the specific food – will be consumed whenever the food is consumed and that exposure will occur every day for a 70 year lifetime. But the food industry wants credit for all the days that a person does *not* consume the food with a carcinogen in it. This is absurd and invites the agency to seek the unknowable.

People have widely divergent, variable and completely unpredictable eating preferences and habits over time.[8] Scientists and surveyors can estimate with some degree of reliability how much of a specific food the average consumer eats at one eating occasion. That is, they can estimate how many potato chips will a potato chip eater eat when a potato chip eater eats potato chips. But no sane consumption expert will argue that there is any way to accurately determine the "frequency" with which an individual will consume a specific food throughout his/her life. That is, no one can know how often the potato chip eater will eat potato chips, or whether the potato chip eater will eat potato chips at any given frequency or even throughout his or her life. That data simply does not exist and estimates can not be manufactured out of thin air. OEHHA's Acrylamide Intake Characterization, in fact, candidly confesses that "*data on the frequency that a food is consumed over a lifetime are not available*."[9]

In the face of not just data uncertainties but a complete absence of any data whatsoever, no regulatory proposal can pass muster.

According to section 25249.10(c) of the statute, the agency and businesses must assume that

---

[8] Indeed, the absurdity of this approach is best illustrated by foods that are *only* consumed for a specific period of one's lifetime. Take baby food, which is designed only to be consumed in the first year of life. Is it the agency's – never mind the industry's – position that a business can permit 60 times the permissible level without any warning at all on the rationale the person will enjoy 69 more years of exposure-free life? To ask the question is to negate it.

[9] Office of Environmental Health Hazard Assessment, *The Characterization of Acrylamide Intake from Certain Foods* (March, 2005) (emphasis added).

an exposure occurs every day for a lifetime of 70 years at the level in question.[10] Prop 65 is a warning statute. It was designed to give people warnings once a daily exposure to a specific food or other medium reached 1/100,000 risk, assuming the exposure would remain at that level every day for a person's 70 year lifetime. This is simple, despite industry's insistence otherwise. The application of risk assessment in the warning calculation is unnecessary and a perversion of Pop 65's intent.

C. The Alternative Risk Level is Completely Unworkable

The terms "bread" and "cereal" have no legal meaning. Indeed they have no practical meaning. For instance, it is and will remain unclear where foods such as pound cake and granola bars fall. Granola is a cereal; if it is bound together in a bar is it something else? Is a zwieback a bread or cracker? Is a crouton still bread?

Even if these etymological matters could be sorted out for the existing food supply, the issue will remain forever. The remarkable ingenuity of the food industry introduces thousands of new food items every year. Many of those increasingly defy traditional categorization. Attempting to keep pace with this issue alone would make this regulation a nightmare for both OEHHA and the food industry. One can easily envision a scenario in which the agency spends the entirety of its resources on safe use determination petition on specific food products to determine whether or not it is a bread or cereal.

From a policy perspective, the breads and cereals distinction is purely arbitrary and fundamentally unfair. As mentioned earlier, the rationale for this distinction is not rooted in science or data, but rather stems from entirely unsupported assumptions about consumer behavior now and how it can be manipulated to create a desired outcome. There is no way to predict how consumers will react to cancer warnings about acrylamide in foods. The only safe assumption is that different people will have different responses to the knowledge that there is a cancer causing chemical in any specific popular processed food product.

Distinguishing breads and cereals as food that are more healthful than others and therefore hiding a ten fold higher cancer risk for these foods is also grossly unfair. It will very likely be challenged as such by the segments of the food industry that are prejudiced by such a distinction, wasting resources and time on a misguided effort.

In addition, like the proposed revised NSRL, the proposed alternative risk level for breads and cereals is unfinished and will have to be revised once OEHHA has the animal data it needs to evaluate cancer risk posed to children and other sensitive populations. Going forward with this regulation at this point, when the science behind it is weak and unfinished, is ill-conceived and will impose unnecessary costs on all involved should OEHHA adopt a new scheme, only to have to change it in a few years.

---

[10] The requirement to give a warning for each day of exposure is found in the remedies section, which defines a violation as a daily matter. There is no basis for assessing penalties on exposures measured over a week, month, year or any other time period.

Last, and perhaps most important, children consume more bread and cereal than do adults on a per body weight basis. Thus an alternative risk level that conceals the presence of a cancer causing substance in these foods can be viewed as a tragedy of sorts. As the revised NSRL document and the Acrylamide Intake Characterization clearly point out, children and infants are believed to be more sensitive to the carcinogenic effects of acrylamide.[11] OEHHA would do a tremendous disservice to Californians and their children if it caves to pressures from the food industry by raising the cancer risk warning level for foods children consume so much of, by concealing from California parents the higher cancer risk in some breads and cereals. While adults have control over the foods they consume, children do not. Of all people, and of all foods, parents should receive warnings about acrylamide in cereals, especially if there is no scientifically valid reason for not warning them.

D. The Alternative Risk Level Provides Misleading Information to Consumers

At present, Prop 65 provides a uniform standard for providing warnings whenever an exposure exceeds 1/100,000 risk of cancer. Hiding the fact of exposure above this level in breads and cereals until they reach a higher warning trigger level at 1/10,000 cancer risk, without in any way notifying the public at places where foods are sold that such a change has occurred, is both misleading and runs counter to the intent of the statute.

The damage will be immense. Two foods, side by side in the market, will have substantially similar cancer risks, yet one may bear a warning while the other does not. Differential warning levels invite precisely the kind of misguided consumer behavior the proposal purports to address. If OEHHA believes that consumers will "choose badly" in their food preferences if given a warning using consistent standards, how can it expect consumers to "choose better" if products bear warnings (or not) based on entirely different standards? The goal of Prop 65 is to enhance consumer information, empower consumer sovereignty, and let consumers choose. Adopting different standards for different chemicals in different exposures and media does not further and legitimate Prop 65's purpose.

E. The Alternative Risk Level Provides the Wrong Incentive to Industry

In the twenty years that Prop 65 has been in existence, time and again, industry has formulated products or changed processes so that the exposure levels are below those set by OEHHA's No Significant Risk Levels (NSRLs) and Maximum Allowable Daily Limits (MADLs). As a single example, the china and ceramics industries freely admit that Prop 65 compelled them to reduce lead content in china and in ceramic glazes below the 0.5 ug/day MADL established by OEHHA. The water faucet and water meter companies did the same. The examples are legion. Business response to Prop 65 has time and again not resulted in more warnings but rather in fewer consumer exposures to known carcinogens and reproductive toxicants.

---

[11] Office of Environmental Health Hazard Assessment (OEHHA, 2005) *The Characterization of Acrylamide Intake from Certain Foods.* California Environmental Protection Agency, pp.1. And Office of Environmental Health Hazard Assessment (OEHHA, 2005) *The No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Acrylamide.* California Environmental Protection Agency, OEHHA. March 2005, pp. 1 and 22.

The same result may be anticipated here. As noted above, Procter & Gamble has already publicly stated it is seeking means to reduce acrylamide formation in Pringles. Food products containing the carcinogen acrylamide will likewise be reformulated. Californians will as a result enjoy a safer food supply because of Prop 65, provided the law is allowed to work as designed.

Adopting a standard that gives a preferred set of consumer products a pass will reduce incentive to reduce exposures.

Moreover, the alternative risk level for breads and cereals is a perversion of the statute's intent. Prop 65 is fundamentally about consumer right-to-know and about choice. Californians overwhelmingly voted to know which products (foods or other) contain cancer-causing chemicals. Food is the one medium – compared for instance to air, water and occupational exposures – over which individuals have considerable control. To hide information in one of the places where individuals enjoy the greatest level of choice in how to respond to a warning is simply perverse.

Arbitrarily allowing a scientifically unsupported 1 in 10,000 cancer risk in any foods is tantamount to giving whole segments of the processed foods industry permission to hide the presence of acrylamide. It is also a denial of what is real. The reality is this: acrylamide is present in highly heat-processed, carbohydrate-rich foods. The cancer risks are undeniable. They are also avoidable if individual consumers are concerned. Californians have a right to be warned. The law is as clear today as it was three years ago when this problem was first detected. Rather than hiding information from consumers, industry has two options: either reduce acrylamide levels below the level at which a warning is required, or provide warnings. Arbitrarily allowing bread and cereal manufacturers a free pass from the warning requirements is neither a valid nor a lawful option.[12]

F. The Alternative Risk Level is Arbitrary – Breads and Cereals Are Not Special

1. The Proposal Is Incomplete in Taking into Account Other Health Benefits and Detriments

The rationale for the proposal is that if cancer warnings are given for breads and cereals, consumers may avoid those foods in droves, resulting in a severe upsetting of necessary dietary and nutritional needs.

As noted, OEHHA has no mandate to consider general public health effects or general nutrition of the populace. But if it chooses nonetheless to do so, it must consider *all* the health and nutritional effects of its regulatory choices.

---

[12] There is also considerable doubt about whether the proposed action is consistent with the Agency's promises made in the settlement of *American Federal of Labor, etc., et al. v. Deukmejian, etc., et al.* Sacramento Superior Court no. 502541 (dated December 23, 1992). In that settlement the agency agreed not to adopt any definition of "no significant risk" for any food unless the it is derived from standards from existing state or federal law and is based upon specific numeric standards that are consistent with existing regulations. If the agency proceeds with this proposal it should expect to have to defend it in court against this promise.

First, the category of "cereals" contains a wide variety of items whose overall nutritional impact is, to put it charitably, dubious. Heavily processed, fortified cereals whose chief ingredient is sugar can be called cereal. Other parents call them candy. In any case, heavily sugared foods in a child's diet are in no small part a contributor to childhood obesity, diabetes and a host of other maladies. If OEHHA is going to embark on a general regulatory program to manipulate dietary choices to achieve overall health outcomes, it will also need to take into account whether highly sugared processed cereals are an essential (or even important) part of a healthy diet such that it wants to hide the cancer risk that might be present in such products.

Second, if OEHHA wants to expand its regulatory portfolio to take a more global approach to the health impacts of acrylamide, it is imperative that OEHHA also fulfill its existing regulatory portfolio and examine whether acrylamide should also be added to the list of reproductive toxicants. It is well known that there are data that might support such a listing. In other respects such data are incomplete. In any case, no decision can be made about acrylamide presence in the food supply and the effect on the total health profile until that listing decision has in fact been made.

IV. Comments on Amendment of 12601. Addition of 12601(b)(1)(E), New "Safe Harbor" Provisions Specific to Warnings for Acrylamide Exposures from Food

A. The Proposed Warning is Unclear and Defeats the Purpose of the Statute

Prop 65 was designed to do nothing more than provide simple warnings about cancer causing chemicals in air, water, soil and consumer products. Once confronted with a Prop 65 warning, the onus has always been on the consumer to educate himself or herself further about the exposure. The law was crafted to do nothing more than give a simple warning about cancer or reproductive risk.

There is no way a warning that is as vague, imprecise and confusing as proposed could ever pass muster as a Prop 65 cancer warning.[13] It fails to do the one essential thing any clear Prop 65 warning does -- it fails to identify specific products that contain acrylamide. Health and Safety Code section 25249.6 requires that warnings be "clear and reasonable." This warning is unclear and unreasonable. It confuses and misleads where it should simply inform. As it reads, this warning obscures the acrylamide issue, frustrates consumers and has the effect of protecting food companies from complying with Prop 65.

This warning would be confusing. The term "starchy foods," for example, is vague and undefined. Consumers can not be expected to know what is meant by "starchy foods." Breaded protein-based food products contain acrylamide. But the term "starchy" does not typically cover breaded protein-based items. Consumers need to identify specific kinds of foods, which they can do only if product names are listed or referenced. The phrase "excessive browning or crisping of some foods" is similarly vague and confusing. Does this cover all foods, such as plantains, eggs, meats, onions? There is also no way to understand what is excessive. These are the kinds of questions vague, imprecise warnings like this engender.

---

[13] The specific warning language referenced can be found in appendices A and B of the proposed regulation 12601(b)(1)(E).

Additionally, giving people only partial information about how cooking contributes to acrylamide formation is misleading. Giving consumers partial and unclear information about anything will lead to erroneous conclusions. That is not the intent of Prop 65. In this instance, a clear and reasonable warning would do nothing more than inform consumers about the presence of a cancer causing chemical in the food product they are purchasing. After reading this proposed warning, one can easily see how consumers might mistakenly conclude that instant potatoes contain no acrylamide because they are boiled or that rice pudding contains acrylamide because it is baked. The point here is that it is irresponsible to give only partial information about the process of acrylamide formation that will mislead consumers.

Furthermore, this proposed warning is inaccurate in that it omits micro waving, broiling and other cooking techniques, while incorrectly implying that baking, roasting, frying and toasting are the only cooking methods that produce acrylamide. This is simply wrong.

With no way to identify acrylamide containing products and no way to distinguish between food products that contain acrylamide and those that do not, consumers might mistakenly avoid all carbohydrate-rich foods (all starches) for fear of the unknown. The virtue of the "clear and reasonable" warnings required by Prop 65 warning is their simplicity. Keep it simple; warn people about the presence of the risk; let them decide for themselves what to do with that information. This proposed "warning" violates all those principles.

B. The Proposed Warning is Unreasonable

This warning is also unreasonable because it hampers consumer choice. One of the hallmarks of Prop 65 is that it gives consumers choice. This proposed warning scheme eliminates that choice. Not only does it confuse consumers but it conceals from them the information they need to exercise any control over the amount of acrylamide they are willing to allow into their diets.

Prop 65 cancer warnings are given to help consumers make choices about exposures to specific products that contain carcinogens. Food is not like air. While we rarely have control over the air we breathe, we always have control over what foods we purchase and ingest. This vague and misleading warning takes a large measure of that choice away. Consumers will be unable to distinguish between product that contain acrylamide and those that do not.

This warning is unreasonable because it presupposes that consumers know how processed foods are made. That is untenable. Food processing techniques of various companies are closely guarded trade secrets. Placing this particular warning in the middle of the cereal isle, for example, is beyond confusing. The general public cannot be expected to know that ready-to-eat cereals are baked at high temperatures. Nor can we expect them to know that Meisli and other such cereal products are generally not baked and contain only negligible amounts of acrylamide. Failing to distinguish the products with acrylamide from the products that do not contain it deprives consumers of the useful information they expressly voted for in 1986.

This warning scheme is unreasonable because it is discriminatory and fundamentally unfair. It protects products with high levels of acrylamide and discriminates against products with little or no acrylamide. It essentially penalizes manufacturers of "starchy foods" that do not contain

acrylamide above the warning level by grouping them with "starchy foods" that have exceedingly high levels.

This warning scheme is unreasonable also because it shifts the burden of providing warnings away from the manufacturers, where the law suggests it preferentially should be[14] because they have both specific knowledge and control over acrylamide levels in their products, and instead, to the retailers. Under this proposal, the manufacturers will have little or no responsibility for the acrylamide content in the foods they produce.

C. Suggestions for a Workable Warning Scheme

The only way a generalized shelf or point of sale warning about acrylamide could work is if it is coupled with some kind of identifier on the package or shelf in the store for each acrylamide-containing food product that requires a warning. This is not just a policy preference. The law requires it.

In the early years of Prop 65, parts of this very industry tried to implement a program in which generalized warnings signs about Prop 65 chemicals in foods were posted at entrances or point of sale. The warnings did not identify any specific products, but instead provided generic information and invited the consumer to look for more information through a toll-free number. The California Attorney General successfully challenged that warning program, colloquially dubbed "1-800-BALONEY." The court that struck it down held that general information, untethered to any specific product, which required the consumer do additional research to uncover what products the warning applied to, did not meet the "clear and reasonable" warning requirement.

This proposal is factually and legally indistinguishable. It will undoubtedly suffer the same fate.

V. Conclusion

Acrylamide in food is a problem. It is real. It is also limited in scope. Most important, it can be controlled. But that will happen only if the processed and prepared food industries are compelled to do so or post warnings. Prop 65 is clear. Either they must reduce the level of acrylamide or they must place clear and reasonable warnings on their products. Vague shelf warnings are completely ill-advised, subvert the intent of the statute and will be challenged in court. Most importantly, it is unreasonable and unlawful for these companies to hide behind a confusing, unreasonable, misleading warning when Californians demanded clear and reasonable warnings.

---

[14] Section 25248.10(f) states. in pertinent part: "In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing [the] chemical. . .into the consumer product in question."

CLEEN COALITION

Altshuler, Berzon, Nussbaum, Rubin & Demain
Baykeeper
Brian Gaffney, Esq.
California Environmental Rights Alliance
Californians for Alternatives to Toxics
Center for Environmental Health
Center on Race Poverty and the Environment
Communities for a Better Environment
Environmental Law Foundation
Ecological Rights Foundation
Michael Freund, Esq.
Lexington Law Group, LLP
Mateel Environmental Justice Foundation
Andrew Packard, Esq.
Physicians for Social Responsibility - Los Angeles
Physicians for Social Responsibility - SF Bay Area
Prof. Cliff Rechtschaffen, Golden Gate University School of Law
The Rose Foundation for Communities and the Environment
Occupational Knowledge